

### **REMARKS**

Reconsideration and withdrawal of the rejections of the claims, in view of the remarks herein, is respectfully requested. Claims 1-67 are now pending in this application.

#### **The 35 U.S.C. § 102 Rejection**

Claims 1-8 were rejected under 35 U.S.C. § 102(b) as being anticipated by Bilcock et al. (J. Biol. Chem., 274:36379 (1999)). This rejection is respectfully traversed.

Bilcock et al. disclose 5 plasmids (Figure 1) with a plurality of restriction endonuclease recognition sites designed to determine whether certain Type II enzymes that recognize a site with 8 specified base pairs require two sites per molecule or can cleave a molecule with only one site.

pAT153, pDB7, and pDB8 in Figure 1 of Bilcock et al., if cleaved with a restriction enzyme that generates a 3' TA overhang (*SgfI* in pAT153, pDB7, and pDB8) and a restriction enzyme which generates blunt ends (*SrfI* in pAT153, pDB7, and pDB8), would not yield a vector backbone where the end generated by *SgfI* could be ligated 5' to an open reading frame, because the restriction enzyme which generates blunt ends in pAT153, pDB7, and pDB8 is 5' to the site for *SgfI*.

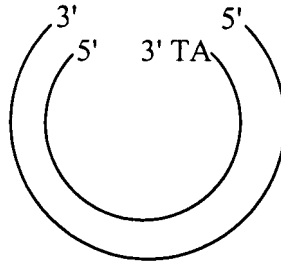
Moreover, pNEB193 and pAB1 (pAB1 is derived from pNEB193) in Figure 1 of Bilcock et al., if cleaved with a restriction enzyme that generates a 3' TA overhang (*PacI* in pNEB193 and pAB1) and *SspI* or *PvuII* in pNEB193 or *PmeI* in pAB1, would not yield a vector backbone where the end generated by *PacI* is 5' to the open reading frame. That is because *SspI* in pNEB193 is 5' to *PacI*, and *PvuII* in pNEB193 and *PmeI* in pAB1 have two sites that flank *PacI*.

Further, pNEB193 and pAB1 do not include a promoter operably linked to an open reading 5' to *PacI*.

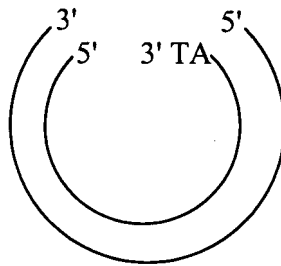
The Examiner asserts that since the restriction enzyme that generates a 3' TA overhang, i.e., *SgfI* in pDB7 and pDB8, generates the same 3' TA overhang on each side or strand of the restriction site, and since the vector is a plasmid and is circular and the *SgfI* cut site is symmetrical, the blunt end cut site is 5' of the *SgfI* site.

If pDB7 is digested with *SgfI* (the only recognition site shown in Figure 1 in Bilcock et al. that, once cleaved, generates a 3' TA overhang) and *SrfI* (the only recognition site shown in

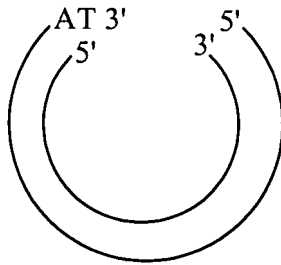
Figure 1 in Bilcock et al. that, once cleaved, generates a blunt end), the following linearized vector is produced:



If pDB8 is digested with *SgfI* and *SrfI* (note there are two cleavage sites for each of those restriction enzymes in pDB8), the following linearized vector is produced:



In contrast, digestion of Applicant's vector with a restriction enzyme that generates a 3' TA overhang, e.g., *SgfI*, and a restriction enzyme that generates a blunt end, yields the following:



Accordingly, withdrawal of the § 102(b) rejection is respectfully requested.

*The 35. U.S.C. § 112, First Paragraph, Rejections*

Claims 1-12 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (a "new matter" rejection). This rejection is respectfully traversed.

The Examiner asserts that the specification as originally-filed does not provide support for "wherein the site in the recombinant vector formed by ligation of the 3' TA overhang and the end generated by *SgfI* is 5' to the open reading frame, and wherein if the vector backbone has an open reading frame that is 5' to the site and is in frame with the open reading frame 3' to the site, the vector backbone includes a promoter that is operably linked to the open reading frame which is 5' to the site."

In this regard, the Examiner is requested to consider Figures 14-16 (showing *SgfI* vectors for cloning and expression or for fusions), page 54, lines 12-16, page 55, line 27-page 56, line 23, page 59, lines 22-25, and page 72, lines 18-24.

Therefore, the phrase "wherein the site in the recombinant vector formed by ligation of the 3' TA overhang and the end generated by *SgfI* is 5' to the open reading frame, and wherein if the vector backbone has an open reading frame that is 5' to the site and is in frame with the open reading frame 3' to the site, the vector backbone includes a promoter that is operably linked to the open reading frame which is 5' to the site" is supported by the specification.

Claims 10-12 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed.

With regard to "X<sub>1</sub>-X<sub>3</sub>, X<sub>2</sub>X<sub>3</sub>G or X<sub>3</sub>GC is a codon which is not a stop codon" in claim 10, "X<sub>1</sub>X<sub>2</sub>X<sub>3</sub> is a codon in an open reading frame which is not a stop codon" in claim 11, and "X<sub>1</sub>X<sub>2</sub>X<sub>3</sub>, X<sub>2</sub>X<sub>3</sub>G or X<sub>3</sub>GT is a codon in an open reading frame which is not a stop codon" in claim 12, the Examiner is requested to reconsider pages 900-901 in Metzler: Biochemistry: the Chemical Reactions of Living Cells, Academic Press, Inc. (1977) (a copy was enclosed with the Amendment filed January 18, 2007), where every codon including stop codons is described.

To provide an adequate written description for a claimed genus, the specification can provide a sufficient description of a representative number of species by an actual reduction to practice, reduction to drawings or by a disclosure of relevant, identifying characteristics, i.e., by a structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics (Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112(1) Written Description Requirement, Fed. Reg., 66, 1099 (2001)). Satisfactory disclosure of a representative number depends on whether one skilled in the art would recognize

that Applicant was in possession of the necessary common attributes or features of the elements possessed by members of the genus (Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112(1) (Written Description Requirement, Fed. Reg., 66, 1099 (2001))).

Applicant has described exemplary restriction enzymes that 1) generate a 3' TA overhang, 2) generate blunt ends, and 3) have infrequent sites in cDNAs and generate blunt ends (see, for example, pages 16-17 and 49-50 of the specification). Thus, one of skill in the art in possession of Applicant's specification would recognize that Applicant was in possession of the relevant common functional and structural characteristics of the recited restriction enzyme recognition sites.

Accordingly, withdrawal of the § 112(1) rejections is respectfully requested.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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By their Representatives,

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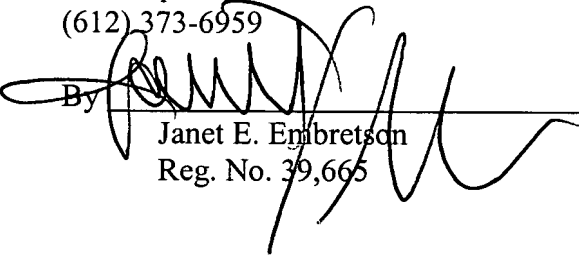
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Date

June 27, 2007

By

  
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**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop RCE, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 27<sup>th</sup> day of June 2007.

Name

Dawn M. Pade

Signature

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